REMARKS

Claim Rejections – 35 USC §102 and 103

Claims 1, 2, 5-7, 9-13, 18, 40, 41, 44-47, 50, 51 and 58 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,669,909 to Zdeblick et al. (hereafter the '909 patent). Additionally, claims 1, 2, 5-15, 17, 18, 20-37, 40, 41, 44-47, 50, 51 and 58 were rejected under 35 U.S.C. §103(a) as being unpatentable over the '909 reference in view of U.S. Patent No. 5,593,409 to Michelson (hereafter the '409 patent). Claims 52, 54, and 56 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,645,598 to Brosnahan (hereafter the '598 patent).

Independent Claim 1 and Dependent Claims 2, 5-12, 14, 15, 17, 18, 20 and 59-61

Independent claim 1, as now amended, recites an elongated generally cylindrical body having a first end wall, a second end wall, and a side wall cooperating to define an interior chamber, with the first and second end walls formed integral with the side wall, and with at least one of the first and second ends having an end wall discontinuity, a side wall discontinuity extending along a length of said body aligned with the end wall discontinuity and configured for nesting with an adjacent spacer, and the side wall discontinuity defining a side wall opening to the interior chamber.

As an initial matter, the Applicant notes that the recitation of "an outer surface defining threaded bone engaging portions" originally recited in independent claim 1 has been removed and reintroduced in new dependent claim 59. This amendment is supported, for example, at page 11, lines 25-28 where it is disclosed that the inclusion of threads is optional. Furthermore, independent claim 1 has been amended to recite that the first and second end walls and the side wall cooperate to define the interior chamber, with "said first and second end walls formed integral with said side wall". Support for this amendment is found, for example, at page 9, lines 12-13 and in the drawing figures.

With regard to the '909 patent, the hollow interior 15 of the fusion device 10 is not defined by first and second end walls and a side wall, with each of the first and second end walls

formed integral with the side wall. To the contrary, although one end of the fusion device 10 is closed off by the end wall 17, the opposite end 16 remains open. The open end 16 does not, therefore, cooperate with the end wall 17 and the side wall to define the hollow interior 15. Additionally, although the '909 patent discloses that the open end 16 may be closed off subsequent to implantation (col. 11, lines 14-16), the structure used to close off the open end 16 would clearly not be "formed integral with" the side wall of the implant, as recited in independent claim 1.

Furthermore, as set forth in the subject application, since the implant body defines a large side wall opening that is sized to provide access to the hollow interior to accommodate loading of a bone growth material therein, the end walls which enclose the hollow interior can be formed integral with the side wall of the implant. (Page 9, lines 8-13; page 12, lines 7-10; page 18, lines 28-29). This is clearly not the case with regard to the implant disclosed in the '909 patent, wherein the end 16 must remain open to allow for the loading of bone growth material into the hollow interior 15. Indeed, the '909 patent specifically teaches that the openings 24, 25 extending through the side walls 22 of the implant are sized to provide vascularization, while still retaining a significant amount of structure to the implant body to support the high axial loads exerted onto the implant body by the adjacent vertebrae. (Col. 6, lines 41-46). The '909 patent also teaches that the vascularization openings 24, 25 can not be sized so large that they compromise the structural integrity of the device or that they permit expulsion of the bone graft material from the hollow interior. (Col. 8, lines 2-6). As a result, the end 16 of the implant body must remain open to provide access to the hollow interior for loading bone graft material into the hollow interior.

Thus, there is no teaching in the '909 patent to form first and second end walls of the implant body integral with the side wall. Likewise, there is no suggestion or motivation to form first and second end walls integral with the side wall, for to do so would not allow the requisite access to the hollow interior to allow for the loading of bone graft material into the hollow interior. Since the implant recited in independent claim 1 includes a side wall opening sized to accommodate loading of a bone growth material therein, the end walls which enclose the hollow interior can be formed integral with the side wall of the implant. Furthermore, the size of the

side wall opening can be quite large without compromising the structural integrity of the implant body since the end walls are each formed integral with the side wall to provide resistance to the loading exerted onto the implant body by the adjacent vertebrae.

For at least the reasons discussed above, the Applicant submits that independent claim 1, as now amended, is distinguishable over the teachings of the '909 patent. Accordingly, the Applicant respectfully requests withdrawal of the rejection of independent claim 1 based on the '909 patent and allowance of independent claim 1.

With regard to the '409 patent, the hollow interior of the fusion implant 100 is not defined by first and second end walls and a side wall, with each of the first and second end walls formed integral with the side wall. To the contrary, although one end of the fusion implant 100 is closed off by an end wall, the opposite end remains open to allow for the loading of a fusion enhancing material. (Col. 10, lines 25-29). The open end does not, therefore, cooperate with the side wall to define the hollow interior. Additionally, although the '409 patent discloses that the open end may be closed off via an end cap 130 (col. 10, lines 25-27), the end cap 130 is clearly not "formed integral with" the side wall of the implant, as recited in independent claim 1.

As indicated above, since the implant body disclosed in the subject application defines a large side wall opening that is sized to provide access to the hollow interior to accommodate loading of a bone growth material therein, the end walls which enclose the hollow interior can be formed integral with the side wall of the implant. (Page 9, lines 8-13; page 12, lines 7-10; page 18, lines 28-29). This is clearly not the case with regard to the implant disclosed in the '409 patent, wherein one end must remain open to allow for the loading of fusion promoting material into the hollow interior. Indeed, although the '409 patent discloses that small openings 128 extend through the implant body in communication with the hollow interior, the openings 128 are clearly not of a size sufficient to permit loading of the fusion promoting material into the hollow interior. The '409 patent also discloses other embodiments of spinal implants. However, each of these other embodiments also includes a cap that closes off an open end of the implant body, and therefore each of these implant embodiments also fails to include first and second end walls which cooperate with a side wall to define an interior chamber and which are formed integral with the side wall, as recited in independent claim 1.

Thus, there is no teaching in the '409 patent to form first and second end walls of the implant body integral with the side wall. Likewise, there is no suggestion or motivation to form first and second end walls integral with the side wall, for to do so would not allow access to the hollow interior to allow for the loading of fusion promoting material into the hollow interior. Since the implant recited in independent claim 1 includes a side wall opening sized to accommodate loading of a bone growth material therein, the end walls which enclose the hollow interior can be formed integral with the side wall of the implant. Furthermore, the size of the side wall opening can be quite large without compromising the structural integrity of the implant body since each of the end walls are formed integral with the side wall to provide resistance to the loading exerted onto the implant body by the adjacent vertebrae.

For at least the reasons discussed above, the Applicant submits that independent claim 1, as now amended, is distinguishable over the teachings of the '409 patent. Accordingly, the Applicant respectfully requests withdrawal of the rejection of independent claim 1 based on the '409 patent and allowance of independent claim 1.

Additionally, claims 2, 5-12, 14, 15, 17, 18, 20, and newly added claims 59-61 depend either directly or indirectly from independent claim 1. As an initial matter, the Applicant notes that dependent claims 5, 6, 17 and 18 have been amended in view of the amendments incorporated into independent base claim 1 and/or to improve their form. Additionally, independent claim 20 has been amended to depend from independent claim 1, and dependent claims 21-33 have been cancelled without prejudice for possible submission in a continuing application.

Dependent claims 2, 5-12, 14, 15, 17, 18, 20 and 59-61 are patentable for at least the reasons supporting the patentability of independent base claim 1. Moreover, further reasons support the patentability of various ones of these dependent claims. For example, dependent claim 60 recites that each of the first and second end walls are fixed and non-removable relative to the elongated body. Neither the '909 patent nor the '409 patent discloses such a feature. Instead, each of these patents discloses a non-integral cap or cover positioned over an open end of the implant body. Such cap or cover would clearly not be "fixed and non-removable" relative to the implant body.

Independent Claim 13 and Dependent Claims 62-70

The Applicant has rewritten dependent claim 13 in independent form and submits that the subject matter recited therein is patentable over the cited patent references, whether considered alone or in combination with one another. Rewritten independent claim 13 recites an elongated generally cylindrical body having a first end, a second end, and a side wall connecting the first end and the second end and defining an interior chamber, a side wall discontinuity extending along a length of the body and configured for nesting with an adjacent spacer, with the side wall discontinuity defining a side wall opening to the interior chamber, and "wherein said side wall opening is sized to extend along at least about 50% of said length of said body to allow passage of osteogenic material into said interior chamber".

As an initial matter, the Applicant notes that the recitation of "an outer surface defining threaded bone engaging portions" originally recited in independent claim 1 has not been carried over into rewritten independent claim 13. Elimination of this feature is supported, for example, at page 11, lines 25-28 where it is disclosed that the inclusion of threads is optional. Additionally, the recitation that the side wall opening is sized to extend along "at least about 50% of said length of said body" is supported, for example, at page 4, lines 21-25 and in Figure 1 of the subject application.

With regard to the '909 patent, the disclosed implant clearly does not include a side wall opening that "is sized to extend along at least about 50% of said length of said body to allow passage of osteogenic material into said interior chamber", as recited in rewritten independent claim 13. Although the '909 patent teaches that the implant body includes openings 24, 25 extending through the side walls 22 of the implant, the openings 24, 25 clearly do not extend along at least about 50% of the length of the implant body. (See Figures 2 and 3). Instead, the openings 24, 25 are sized to provide vascularization, while still retaining a significant amount of structure to the implant body to support the high axial loads exerted onto the implant body by the adjacent vertebrae. (Col. 6, lines 41-46). Indeed, the '909 patent specifically teaches that the vascularization openings 24, 25 can not be sized so large as to compromise the structural integrity of the device or permit expulsion of the bone graft material from the hollow interior. (Col. 8, lines 2-6).

As a result, the '909 patent fails to disclose, and in fact appears to teaches away from, the concept of providing the openings 24, 25 with a size which extends along at least about 50% of the length of the implant body to allow passage of osteogenic material into the interior chamber. Instead, as discussed above with regard to independent claim 1, the end 16 of the implant body remains open to allow for the loading of bone growth material into the hollow interior 15. It is neither contemplated nor desired that the openings 24, 25 be sized to allow passage of bone growth material therethrough and into the hollow interior 15, for to do so would compromise the structural integrity of the implant body and would permit expulsion of the bone graft material from the hollow interior. Additionally, although the elongate slots 27 extending through the threaded upper and lower portions of the implant body appear to extend along a significant portion of the implant length, the slots 27 are not defined through a side wall discontinuity, as required by independent claim 13. For at least these reasons, the Applicant submits that rewritten independent claim 13 is distinguishable over the teachings of the '909 patent. Accordingly, the Applicant respectfully requests withdrawal of the rejection of claim 13 based on the '909 patent and allowance of rewritten independent claim 13.

With regard to the '409 patent, this implant also does not include a side wall opening that "is sized to extend along at least about 50% of said length of said body to allow passage of osteogenic material into said interior chamber", as recited in rewritten independent claim 13. Although the '409 patent teaches that the implant body includes openings 128 extending through the implant body in communication with the hollow interior, the openings 128 are quite small and clearly are not sized to extend along at least about 50% of the length of the body, nor are the openings 128 of a size sufficient to allow loading of osteogenic material into the hollow interior chamber. The '409 patent also discloses other embodiments of spinal implants. However, each of these other embodiments likewise fails to disclose openings that satisfy the features associated with the side wall opening recited in rewritten independent claim 13. Instead, as discussed above with regard to independent claim 1, the implant body includes an end that remains open to allow for the loading of bone growth material into the hollow interior. It is neither contemplated nor desired that the openings 128 be sized to so as to extend along at least about 50% of the implant length to allow passage of fusion promoting material. For at least these reasons, the Applicant

submits that rewritten independent claim 13 is distinguishable over the teachings of the '409 patent. Accordingly, the Applicant respectfully requests withdrawal of the rejection of claim 13 based on the '409 patent and allowance of rewritten independent claim 13.

Additionally, newly added claims 62-70 depend either directly or indirectly from rewritten independent claim 13. New dependent claims 62-70 are patentable for at least the reasons supporting the patentability of rewritten independent base claim 13. Moreover, further reasons support the patentability of various ones of these dependent claims. For example, dependent claim 63 recites that the first end comprises a first end wall, the second end comprises a second end wall, and that each of the first and second end walls cooperates with the side wall to define the interior chamber. Dependent claim 64 further recites that each of the first and second end walls are formed integral with the side wall, and dependent claim 65 further recites that the each of the first and second end walls are fixed and non-removable relative to the elongated body. As discussed above with regard to independent claim 1, neither the '909 patent nor the '409 patent discloses or suggests such features. Instead, each of these patents discloses an open end over which is positioned a non-integral cap or cover that is clearly not fixed and non-removable relative to the implant body.

Independent Claim 34 and Dependent Claims 35-37 and 71-74

Independent claim 34, as now amended, recites a first interbody fusion spacer having a first elongated body and having a circumference with external threads, a first end defining a first end wall, a second end defining a second end wall, and a first side wall formed integral with the first end wall and said second end wall and defining a first interior cavity, at least one of the end walls having a discontinuity extending along a length of the body and into the side wall, with the discontinuity defining an opening in communication with the first interior cavity, and with the side discontinuity and the end wall discontinuity extending about the circumference of the body to substantially the same extent, and a second interbody fusion spacer nested within the discontinuity defined by the first interbody fusion spacer. As an initial matter, independent claim 34 has been amended to recite the "side wall formed integral with said first end wall and said

second end wall". Support for this amendment is found, for example, at page 9, lines 12-13 and in the drawing figures.

As discussed above with regard to independent claim 1, the '909 patent discloses a fusion device 10 wherein the hollow interior 15 of the fusion device is not defined by first and second end walls and a side wall, with each of the first and second end walls formed integral with the side wall. To the contrary, although one end of the fusion device 10 is closed off by the end wall 17, the opposite end 16 remains open to allow for the loading of a bone growth promoting substance into the hollow interior of the implant. Therefore, the open end does not define an interior cavity with the end wall 17 and the side wall. Additionally, although the '909 patent discloses that the open end 16 may be closed off subsequent to implantation, the structure used to close off the open end 16 would clearly not be "formed integral with" the side wall of the implant, as recited in independent claim 34. For at least this reason, the Applicant submits that independent claim 34, as now amended, is distinguishable over the teachings of the '909 patent. Accordingly, the Applicant respectfully requests withdrawal of the rejection of independent claim 34 based on the '909 patent and allowance of independent claim 34.

As also discussed above with regard to independent claim 1, the '409 patent discloses a fusion implant 100 wherein the hollow interior of the fusion implant is likewise not defined by first and second end walls and a side wall, with each of the first and second end walls formed integral with the side wall. To the contrary, although one end of the fusion implant 100 is closed off by an end wall, the opposite end remains open to allow for the loading of a fusion enhancing material into the hollow interior of the implant. The open end does not, therefore, cooperate with the side wall to define the hollow interior. Additionally, although the '409 patent discloses that the open end may be closed off via an end cap 130 (col. 10, lines 25-27), the end cap 130 is clearly not be "formed integral with" the side wall of the implant, as recited in independent claim 34. For at least this reason, the Applicant submits that independent claim 34, as now amended, is distinguishable over the teachings of the '409 patent. Accordingly, the Applicant respectfully requests withdrawal of the rejection of independent claim 34 based on the '409 patent and allowance of independent claim 34.

Additionally, claims 35-37, and newly added claims 71-74, depend either directly or

indirectly from independent claim 34. As an initial matter, the Applicant notes that dependent claims 35 and 37 have been amended in view of the amendments incorporated into independent base claim 34 and/or to improve their form.

Dependent claims 35-37 and 71-74 are patentable for at least the reasons supporting the patentability of independent base claim 34. Moreover, further reasons support the patentability of various ones of these dependent claims. For example, claim 71 recites that each of the first and second end walls are fixed and non-removable relative to the elongated body. As discussed above with regard to dependent claim 60, this feature is neither disclosed or suggested by either the '909 patent or the '409 patent. Additionally, claim 73 recites that the side wall opening is sized to extend along at least about 50% of the length of the body to allow passage of osteogenic material into the interior cavity. As discussed above with regard to independent claim 13, this feature is neither disclosed or suggested by either the '909 patent or the '409 patent.

Independent Claim 40 and Dependent Claims 41, 44, 45 and 58

Independent claim 40 and dependent claims 41, 44, 45 and 58 have been cancelled without prejudice for possible submission in a continuing application.

Independent Claim 46 and Dependent Claims 47, 50 and 51

Independent claim 46 has been amended in a manner virtually identical to that of independent claim 34. Accordingly, independent claim 46 is patentable for at least the reasons set forth above with regard to independent claim 34, and the Applicant therefore respectfully requests withdrawal of the rejection of independent claim 46 and allowance the same.

Additionally, claims 47, 50 and 51 depend from independent claim 46, and are submitted to be patentable for at least the reasons supporting the patentability of independent base claim 46. The Applicant notes that dependent claim 51 has been amended in view of the amendments incorporated into independent base claim 46 and/or to improve its form.

Independent Claim 52 and Dependent Claims 54, 56, 58 and 75

Independent claim 52, as now amended, recites an elongate, generally cylindrical body having external threads and comprised of metal and having end walls and a side wall extending between the end walls, with the side wall and the end walls defining an interior chamber, and with the side wall defining a main side wall opening configured to extend along at least about 50% of the length of the body for passage of osteogenic material into the interior chamber, and further defining a plurality of secondary side wall openings communicating with the interior chamber for bone ingrowth into the interior chamber. The end walls each have an external profile comprising a first portion defining an arc of a circle extending from 180° to 324° around the circle, and a second portion defining a concave surface with the main side wall opening extending through the concave surface and into communication with the interior chamber, and with the side wall having an external profile defining an arc of a circle extending from 180° to 324° around the circle and aligned with the arc defined by the end walls.

As an initial matter, support for the added feature regarding the main side wall opening configured "to extend along at least about 50% of the length of said body" for passage of osteogenic material into the interior chamber is found, for example, at page 4, lines 21-25 and in Figure 1 of the subject application. Additionally, support for the added feature regarding the plurality of secondary side wall openings communicating with the interior chamber for bone ingrowth into the interior chamber is found, for example, at page 10, lines 26-28 and in Figures 1 and 3 of the subject application.

As discussed above with regard to rewritten independent claim 13, the '909 patent fails to disclose or suggest that the implant body includes a side wall opening that is configured "to extend along at least about 50% of the length of said body" for passage of osteogenic material into the interior chamber, as recited in rewritten independent claim 52. To the contrary, the '909 patent teaches that the implant body includes openings 24, 25 extending through the side walls 22 of the implant that are sized to provide vascularization, while still retaining a significant amount of structure to the implant body to support the high axial loads exerted onto the implant body by the adjacent vertebrae. Indeed, the '909 patent specifically teaches that the vascularization openings 24, 25 can not be sized so large as to compromise the structural

integrity of the device or permit expulsion of the bone graft material from the hollow interior. (Col. 8, lines 2-6). As a result, the '909 patent fails to disclose, and in fact appears to teaches away from, the concept of providing the openings 24, 25 with a size which extends along at least about 50% of the length of the implant body to allow passage of osteogenic material into the interior chamber. For at least these reasons, the Applicant submits that amended independent claim 52 is distinguishable over the teachings of the '909 patent, and allowance of the same is respectfully requested.

As also discussed above with regard to the '409 patent, this implant likewise does not include a side wall opening that is configured to extend along at least about 50% of the length of the implant body. Although the '409 patent teaches that the implant body includes openings 128 extending through the implant body in communication with the hollow interior, the openings 128 are quite small and clearly are not sized to extend along at least about 50% of the length of the body, nor are the openings 128 of a size sufficient for passage of osteogenic material into the hollow interior chamber. For at least these reasons, the Applicant submits that amended independent claim 52 is distinguishable over the teachings of the '409 patent, and allowance of the same is respectfully requested.

Finally, with regard to the rejection of independent claim 52 as being unpatentable over the '598 patent to Brosnahan, the Applicant respectfully disagrees with the assertion set forth in the Office Action that "it would have been obvious to one having ordinary skill in the art at the time the invention was made to position the opening in the concave surface". (Page 5 of the Office Action). To the contrary, the through slot 40 illustrated in Figure 14 of the '598 patent is clearly used to promote bone growth through the fusion device between the adjacent vertebrae. (Col. 5, lines 31-45). Accordingly, in order to accomplish this objective, the openings of the slot 40 must be positioned directly adjacent the vertebrae in order for bone through growth to occur through the fusion device. As a result, there is no suggestion, and indeed there would be no motivation whatsoever, to position the slots 40 so as to extend between the concave side walls 48b, 50b, for to do so would prevent, or at least the very least significantly hinder, bone growth through the fusion device.

Nevertheless, the Applicant has amended independent claim 52 to further recite a plurality of secondary side wall openings communicating with the interior chamber for bone ingrowth into the interior chamber. These secondary bone ingrowth openings are in addition to the main side wall opening which is sized for passage of osteogenic material into the interior chamber. Notably, the'598 patent fails to disclose both a main side wall opening sized for passage of osteogenic material into an interior chamber and a plurality of secondary side wall openings communicating with the interior chamber for bone ingrowth into the interior chamber. The Applicant therefore submits that independent claim 52 is patentable over the '598 patent. Accordingly, withdrawal of the rejection of independent claim 52 based on the '909 patent and allowance of the same is respectfully requested.

Additionally, dependent claims 54 and 56 and newly added claim 75 depend either directly or indirectly from amended independent claim 52. As an initial matter, claims 54 and 56 have been amended to improve their form. Additionally, dependent claims 54, 56 and 75 are patentable for at least the reasons supporting the patentability of amended independent base claim 52. Moreover, further reasons support the patentability of various ones of these dependent claims. For example, dependent claim 54 recites that the end walls are formed integral with the side wall. As discussed above, this feature is neither disclosed nor suggested in the '909 patent or the '409 patent. Additionally, dependent claim 56 recites that the side wall has surface features for resisting expulsion from an intervertebral space. Once again, this feature is neither disclosed nor suggested in the '909 patent or the '409 patent.

New Independent Claim 76 and Dependent Claims 77-79

Independent method claim 76 has been added to the subject application and recites, in pertinent part, the step of providing a first interbody fusion spacer including an elongated body having a first end, a second end and a side wall connecting the first end and the second end, the body defining an interior chamber, a side wall discontinuity extending along a length of the body and defining a side wall opening communicating with the interior chamber, the side wall opening sized to extend along at least about 50% of the length of the body to allow passage of osteogenic material into the interior chamber.

Notably, new independent claim 76 includes features that are very similar to those recited in rewritten independent claim 13. Accordingly, independent claim 76 is submitted to be patentable for at least the reasons set forth above with regard to independent claim 13, and the Applicant therefore respectfully requests allowance of independent claim 76. Additionally, new claims 77-79 depends from independent claim 76, and are submitted to be patentable for at least the reasons supporting the patentability of independent base claim 76.

New Independent Claim 80 and Dependent Claims 81-82

Independent method claim 80 has been added to the subject application and recites, in pertinent part, the step of providing a first interbody fusion spacer including an elongated body having a first end, a second end, and a side wall cooperating to define an interior chamber, with the first and second end walls formed integral with the side wall such that the first and second end walls are fixed and non-removable relative to the elongated body, and at least one of the first end wall and the second end wall having an end wall discontinuity, and a side wall discontinuity extending along a length of the body aligned with the end wall discontinuity and configured for nesting with an adjacent spacer, and with the side wall discontinuity defining a side wall opening to the interior chamber.

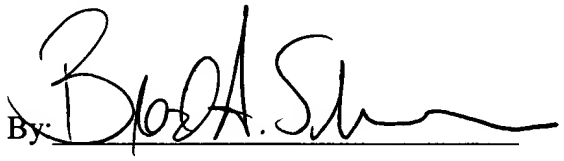
Notably, new independent claim 80 includes features that are very similar to those recited in amended independent claim 1. Accordingly, independent claim 80 is submitted to be patentable for at least the reasons set forth above with regard to independent claim 1, and the Applicant therefore respectfully requests allowance of independent claim 80. Additionally, new claims 81-82 depend from independent claim 80, and are submitted to be patentable for at least the reasons supporting the patentability of independent base claim 80.

CONCLUSION

In view of the foregoing amendments and remarks, it is respectfully submitted that the Applicant's application is now in condition for allowance with pending claims 1, 2, 5-15, 17, 18, 20, 34-37, 40, 46, 47, 50-52, 54, 56 and 59-82.

Reconsideration of the subject application is respectfully requested. Timely action towards a Notice of Allowability is hereby solicited. The Examiner is encouraged to contact the undersigned by telephone to resolve any outstanding matters concerning the subject application.

Respectfully submitted,

By: 

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